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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,046	09/25/2006	Nnochiri N. Ekwuribe	014811-673.119US	8968

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
02/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,046	EKWURIBE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,15,30 and 33-40* is/are pending in the application.

4a) Of the above claim(s) *33-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,15,30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/9/09; 10/5/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on October 5, 2009 has been entered.

Applicants' Response to the Election of Species Requirement filed December 30, 2009 and Supplemental Response filed January 7, 2010 are acknowledged. Applicants have elected the non-azo bonded 5-ASA compound, i.e., 5-amino salicyclic acid, as the first therapeutic agent and the 4-APAA compound azo bonded to a 5-ASA compound that is known as APAZA as the second therapeutic agent.

Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, the subject matter presently under consideration are those pharmaceutical compositions comprising the combination of 5-ASA and APAZA and methods of treating an inflammatory colon condition, claims 1-9, 15 and 30. Those pharmaceutical compositions and methods of treatment drawn to the administration of other, non-elected therapeutic agents, and claims 33-40, are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. A second therapeutic agent that is the elected "4-APAA compound **azo bonded** to a 5-

ASA compound" is not recited in claims 33-40. Re-affirmation of the elections is requested when Applications respond to this Office Action.

Information Disclosure Statements filed September 9, 2009 and October 5, 2009 are further acknowledged and have been reviewed.

Those objections and rejections set forth in previous Office Actions that are not herein reiterated are withdrawn. The following rejections constitute the only rejections presently applied to the instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 15 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 7,425,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 of the patent is drawn to a pharmaceutical

composition that is an oral solution comprising APAZA (5-(4-carboxymethylphenylazo)-2-hydroxy-benzoic acid and 5-ASA. The open language of the present claims allows for the inclusion of additional active agents.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 30 lacks clarity because it is drawn to a treatment of an inflammatory **colon condition** yet the amount of the pharmaceutical composition administered is sufficient to reduce the inflammatory **gastro**intestinal condition.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8, 9, 15 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Ekwuribe et al., U.S. Patent 7,425,578.

Ekwuribe teaches a pharmaceutical composition comprising 5-aminosalicylic acid and APAZA in the form of an oral solution for use in the treatment of an inflammatory colon condition. See claim 16, column 18, as well as the Abstract. Rectal administration is disclosed in column 7, line 26, as required by instant claims 8 and 9.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 15 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwuribe et al., U.S. Patent 7,425,578, in view of The Merck Manual.

Ekwuribe teaches a pharmaceutical composition comprising 5-aminosalicylic acid and APAZA in the form of an oral solution for use in the treatment of an inflammatory colon condition. See claim 16, column 18, as well as the Abstract. Rectal administration is disclosed in column 7, line 26, as required by instant claims 8 and 9.

The Merck Manual teaches the pharmacology of the presently claimed compounds. Hydrolysis of the azo bond of the presently claimed second therapeutic agent and the enzymatic action of bacterial flora in the lower ileum and colon are discussed. See the last paragraph on page 310 and the first paragraph on page 311. Delayed–release coating, such as an acrylic polymer, or encapsulation in ethylcellulose microgranules, allows manipulation of the timing of drug release at a targeted site. Multiple drug therapy in the treatment of inflammatory bowel diseases with agents such as steroids, antibiotics and probiotic agents and organisms is conventional practice.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 10, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614